UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
1600 EAST LAMAR BOULEVARD
ARLINGTON, TEXAS 76011-4511

June 26, 2020

EA-20-065
EN 54250

Ms. Jodi Vanderpool, Vice President
Quality Operations and Patient Safety
St. Luke's Regional Medical Center
190 East Bannock Street
Boise, ID 83712

SUBJECT: NRC INSPECTION REPORT 030-32196/2020-001

Dear Ms. Vanderpool:

This letter and the enclosed inspection report refer to the routine unannounced inspection conducted on February 24-28, 2020, at your facilities in Boise and Meridian, Idaho, with continued in-office review through April 20, 2020. The inspection was performed to examine activities conducted under your license as they relate to public health and safety and to confirm compliance with the U.S. Nuclear Regulatory Commission's (NRC's) rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of an examination of selected procedures and representative records, observation of licensed activities and facilities, independent radiation measurements, and interviews with personnel.

The inspection also reviewed a medical event that occurred on February 20, 2019, involving a discrepancy between the prescribed and administered activity for a therapeutic administration of radium-223. After your staff discovered the medical event, it was reported to the NRC's Operations Center on August 30, 2019, Event Notification 54250.

The enclosed report presents the results of this inspection. The inspector discussed the preliminary inspection findings with you and members of your staff on February 28, 2020, at the conclusion of the onsite portion of the inspection. A final exit briefing was conducted telephonically you and members of your staff on June 25, 2020.

Based on the results of this inspection, three apparent violations were identified and are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The apparent violations involve the failure to: (1) monitor individuals' exposure from licensed and unlicensed radiation sources; (2) implement certain elements of your radiation protection program; and (3) provide instruction to individuals who were likely to receive in a year an occupational dose in excess of 100 mrem.

Following the onsite inspection, you provided the NRC with an analysis of the estimated radiation doses received by four individuals during calendar years 2012-2019 and determined that none of the individuals exceeded the NRC's regulatory limits for occupational dose during

any of the years evaluated. However, because of the programmatic nature of the failures regarding the implementation of your dosimetry program and lack of adequate oversight of licensed activities, a substantial potential existed for individuals to exceed the NRC's regulatory limits for occupational radiation dose during multiple years.

Before the NRC makes its enforcement decision, we are providing you an opportunity to: (1) respond in writing to the apparent violations addressed in the inspection report within 30 days of the date of this letter; (2) request a predecisional enforcement conference (PEC); or (3) request alternative dispute resolution (ADR). If a PEC is held, it will be open for public observation and the NRC will issue a meeting Notice to announce the time and date of the conference. Please contact Ms. Patricia A. Silva, Chief, Materials Inspection Branch, at 817-200-1455 within 10 days of the date of this letter to notify the NRC of your intended response to either provide a written response, participate in a PEC, or pursue ADR. A PEC should be held within 30 days and an ADR session within 45 days of the date of this letter.

If you choose to provide a written response, it should be clearly marked as a "Response to Apparent Violations in NRC Inspection Report 030-32196/2020-001; EA-20-065" and should include for each apparent violation: (1) the reason for the apparent violation or, if contested, the basis for disputing the apparent violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; and (4) the date when full compliance will be achieved. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response.

Your response should be sent to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with identical copies mailed to Ms. Mary Muessle, Director, Division of Nuclear Materials Safety, Region IV, 1600 East Lamar Boulevard, Arlington, TX 76011, and emailed to R4Enforcement@nrc.gov, within 30 days of the date of this letter. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a PEC.

If you choose to request a PEC, the conference will afford you the opportunity to provide your perspective on these matters and any other information that you believe the NRC should take into consideration before making an enforcement decision. The decision to hold a PEC does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference would be conducted to obtain information to assist the NRC in making an enforcement decision. The topics discussed during the conference may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned.

In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful in preparing your response. You can find the Information Notice on the NRC Web site at https://www.nrc.gov/docs/ML0612/ML061240509.pdf.

In lieu of a PEC, you may request ADR with the NRC in an attempt to resolve this issue. Alternative dispute resolution is a general term encompassing various techniques for resolving conflicts using a neutral third party. The technique that the NRC employs is mediation.

Mediation is a voluntary, informal process in which a trained neutral mediator works with parties to help them reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral mediator who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues, clear up misunderstandings, be creative, find areas of agreement, and reach a final resolution of the issues.

Additional information concerning the NRC's ADR program can be obtained at http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html. The Institute on Conflict Resolution at Cornell University has agreed to facilitate the NRC's program as a neutral third party. Please contact the Institute on Conflict Resolution at 877-733-9415 within 10 days of the date of this letter if you are interested in pursuing resolution of this issue through ADR.

Please be advised that the number and characterization of apparent violations described in the enclosed inspection report may change as a result of further NRC review. You will be advised by separate correspondence of the results on our deliberations in this matter.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter, its enclosure, and any responses will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, any response should not include any personal privacy or proprietary information so that it can be made available to the public without redaction.

If you have any questions concerning this matter, please contact Ms. Patricia A. Silva of my staff, at 817-200-1455.

Sincerely,

Mary C. Muessle

Digitally signed by Mary C. Muessle
Date: 2020.06.26 12:55:48 -05'00'

Mary Muessle, Director
Division of Nuclear Materials Safety

License No.: 11-27312-01
Docket No.: 030-32196

Enclosure:
NRC Inspection Report 030-32196/2020-001

cc w/Enclosures:
Mr. Mark Dietrich
State of Idaho Radiation Control Program

NRC INSPECTION REPORT 030-32196/2020-001 DATED June 26, 2020

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Keyword:
By: JFK ☒ Yes ☐ No ☒ Publicly Available ☐ Sensitive

OFFICE	RIV:MIB	C:MIB	ACES:TL	RC	D:DNMS
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SIGNATURE	*/RA/*	/RA/	/RA/	*/RA/*	Mary C. Muessle Digitally signed by Mary C. Muessle Date: 2020.06.26 12:56:25 -05'00'
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U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

Docket No.:	030-32196
License No.:	11-27312-01
Inspection Report No.:	030-32196/2020-001
EA No.:	EA-20-065
EN No.:	EN 54250
Licensee:	St. Luke's Regional Medical Center
Locations Inspected:	St. Luke's Regional Medical Center 190 E. Bannock Street Boise, Idaho St. Luke's Cancer Institute 100 E. Idaho Street Boise, Idaho St. Luke's Saltzer Medical Imaging 3277 East Louise Drive, Suite 100 Meridian, Idaho
Inspection Dates:	Onsite February 24-28, 2020, with in-office review through April 20, 2020
Exit Meeting Date:	June 25, 2020
Inspector:	Janine F. Katanic, PhD, CHP Senior Health Physicist Materials Inspection Branch Division of Nuclear Materials Safety, Region IV
Approved by:	Patricia A. Silva Chief, Materials Inspection Branch Division of Nuclear Materials Safety, Region IV
Attachment:	Supplemental Inspection Information

Enclosure

EXECUTIVE SUMMARY

St. Luke's Regional Medical Center
NRC Inspection Report 030-32196/2020-001

During February 24-28, 2020, the NRC performed an unannounced, routine inspection of St. Luke's Regional Medical Center facilities in Boise and Meridian, Idaho. The scope of the inspection was to examine the activities conducted under the license and to confirm compliance with the NRC's rules and regulations and with the conditions of the St. Luke's Regional Medical Center license. The inspection also included additional review of: (1) the licensee's corrective actions to address previously issued violations; (2) a February 20, 2019, medical event involving the therapeutic use of radium-223 dichloride; and (3) the licensee's personnel dosimetry program.

Program Overview

St. Luke's Regional Medical Center is authorized under NRC Materials License 11-27312-01, to possess and use byproduct material for diagnostic and therapeutic medical use under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35 at its facilities in Idaho.

Follow-up from NRC's 2017 Inspection

The inspector reviewed the licensee's corrective actions related to two previously identified Severity Level IV violations regarding the licensee's failure to: (1) confine the use and possession of radioactive material to the specific sealed sources and model numbers authorized in the license; and (2) assure operation of electrical interlocks at the remote afterloader unit room entrance. Based on the results of the inspection, both violations are considered closed.

Medical Event

On August 30, 2019, the licensee notified the NRC of a medical event that met the criteria in 10 CFR 35.3045(a)(1)(i) (Event Number 54250). The medical event occurred on February 20, 2019, but was not discovered until the licensee performed an audit on August 29, 2019. On September 3, 2019, the licensee provided the NRC with a written report regarding the medical event. The licensee determined that the patient was administered the correct activity of radium-223 dichloride based on the patient's weight, but that an incorrect value of activity or dosage was documented on the written directive.

The licensee implemented corrective actions following the discovery of the medical event, including providing additional training to relevant staff regarding its policy for the completion and preparation of written directives, and that written directives will be audited quarterly.

Dosimetry Program

The inspector identified that four Interventional Radiology physicians involved with yttrium-90 administrations had not consistently worn or had improperly stored their assigned personnel dosimeters, which are intended to be used to monitor radiation dose to the individuals. At the NRC's request, the licensee performed a retrospective evaluation of the radiation dose received by the IR physicians from calendar years 2012 through 2019. The licensee's evaluation concluded that there were no exposures in excess of the NRC's regulatory limit for any Interventional Radiology physician for any year evaluated.

Three apparent violations were identified regarding the licensee's failure to: (1) monitor individuals' occupational exposure to radiation and radioactive material; (2) implement a radiation protection program commensurate with the scope and extent of licensed activities; and (3) provide instruction to occupationally exposed individuals.

The root cause of the failures associated with the St. Luke's Regional Medical Center dosimetry program can be attributed to the licensee's failure to develop and implement a radiation protection program, including policies, procedures, and training programs, commensurate with the scope and extent of licensed activities.

Following the onsite inspection, the licensee implemented several corrective actions to address the personnel dosimetry deficiencies. These corrective actions included providing additional oversight of the St. Luke's Regional Medical Center personnel dosimetry program and providing individuals with instruction regarding the licensee's policies and the NRC's regulations regarding personnel monitoring.

REPORT DETAILS

1 Program Overview (Inspection Procedures (IPs) 87103, 87131, 87132)

1.1 Program Scope

St. Luke's Regional Medical Center (SLRMC or licensee) is authorized under NRC Materials License 11-27312-01 to possess and use byproduct material for diagnostic and therapeutic medical use under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35 at its facilities in Idaho.

1.2 Observations and Findings

During February 24-28, 2020, the inspector performed an unannounced, routine inspection of SLRMC. The inspection included the SLRMC main hospital and St. Luke's Cancer Institute in Boise, Idaho, as well as a SLRMC diagnostic imaging center in Meridian, Idaho. The scope of the inspection was to examine the activities conducted under the license and to confirm compliance with the NRC's rules and regulations and with the conditions of the SLRMC license.

Within these areas, the inspection consisted of a selected examination of procedures and representative records, observations of licensed activities, independent radiation measurements, and interviews with personnel. The inspector also obtained and reviewed additional documents provided by the licensee following the onsite inspection.

This inspection also included additional review of: (1) the licensee's corrective actions to address previously issued violations; (2) a February 20, 2019, medical event involving the use of radium-223 dichloride (Ra-223); and (3) the licensee's personnel dosimetry program.

2 Follow-up from NRC's 2017 Inspection (IP 87132)

2.1 Inspection Scope

On February 24-28, 2020, the inspector performed an unannounced, routine inspection of SLRMC. This inspection included a review of the licensee's corrective actions to address previously issued violations. To evaluate this matter, the inspector reviewed records, procedures, and documents maintained by the licensee, observed licensed activities, and interviewed personnel.

2.2 Background

On December 14, 2017, NRC Inspection Report and Notice of Violation (NOV) 030-32196/2017-001 was issued (ADAMS Accession No. ML17348B491). The Inspection Report and NOV identified apparent violations related to the licensee's implementation of its physical security program to comply with 10 CFR Part 37 and two Severity Level IV violations related to the licensee's brachytherapy programs under 10 CFR Part 35.

On March 29, 2018, the NRC issued "NOV and Proposed Imposition of Civil Penalty - $7,250, NRC Inspection Report 030-32196/2017-001, EA-17-181" (ADAMS Accession No. ML18088A059). The NOV issued on March 29, 2018, identified an escalated

enforcement action related to the licensee's implementation of its physical security program related to 10 CFR Part 37.

On September 24-25, 2018, the NRC performed an onsite inspection to review the licensee's corrective actions related to the physical security program. On November 2, 2018, the NRC issued NRC Inspection Report 030-32196/2018-002 which closed the escalated enforcement action (ADAMS Accession No. ML18306A660).

On July 23-24, 2019, the NRC performed an onsite inspection to observe the removal of a radioactive material quantity of concern from SLRMC. On August 13, 2019, the NRC issued Inspection Report 030-32196/2019-001, indicating that no violations were identified (ADAMS Accession No. ML19296B790).

The two Severity Level IV violations related to the licensee's brachytherapy programs that were issued in the December 14, 2017, NRC Inspection Report and NOV remained open and were reviewed during this inspection.

2.3 Observations and Findings

2.3.1 10 CFR 35.400 Manual Implant Brachytherapy

The December 14, 2017, Inspection Report and NOV identified a Severity Level IV violation of License Condition 7.D of NRC License 11-27312-01, which specifies the physical form of byproduct material that is authorized to be possessed and used by the licensee for manual brachytherapy procedures permitted by 10 CFR 35.400 (030-32196/2017-001-05).

As an immediate corrective action, on September 30, 2017, the licensee submitted a license amendment request, which was subsequently approved by the NRC on December 27, 2017, to have the Theragenics Corporation Model AgX100 radioactive seed added to the NRC license as an authorized radioactive source under 10 CFR 35.400.

The licensee responded to the NOV in a letter dated January 12, 2018 (ADAMS Accession No. ML1808B371). The licensee stated that as a corrective action to prevent recurrence, at the time of ordering any brachytherapy sources, the ordering physicist would utilize a checklist to prompt a review of the NRC license to verify that the model number is listed in the NRC license.

The inspector reviewed the licensee's implementation of its manual brachytherapy program performed under 10 CFR 35.400. Since the date of the previous NRC routine inspection, the only activity performed under 10 CFR 35.400 was permanent manual brachytherapy for prostate cancer. The inspector did not review any permanent manual brachytherapy cases performed in 2018 because those files were not easily retrievable during the inspection. For calendar year (CY) 2019, only two permanent manual brachytherapy procedures were performed. The inspector reviewed both cases in detail with one of the SLRMC Authorized Medical Physicists (AMP).

For both of the permanent manual brachytherapy procedures performed in CY 2019, the inspector's review included, but was not limited to the licensee's: preplanning dosimetry calculations; established dosimetry goals; pre-implantation written directive;

brachytherapy source calibration certificates; post-implantation written directive; radiation survey records; post-implantation radiation dose determinations; and radioactive material disposal records. Each procedure was evaluated by the AMP for dose to the target and dose to unintended tissues/organs. Both procedures had properly prepared written directives and were evaluated post-implantation for quality and for comparison to the NRC's medical event criteria. Both procedures were of high quality and did not result in any medical events. The AMPs used the "Prostate Radioactive Seed Implant" checklist to verify that pre-implantation, day of implant, and post-implantation regulatory requirements were fulfilled.

Both of the permanent manual brachytherapy procedures performed in CY 2019 utilized Theragenics Corporation Model AgX100 iodine-125 radioactive seeds, which were authorized on the SLRMC NRC license following the previous NRC inspection. The licensee's "Prostate Radioactive Seed Implant" checklist contained an item for verifying that the radioactive seeds to be used are authorized on the current NRC license.

The licensee's corrective actions were sufficient to address and to prevent recurrence of the previously identified violation regarding the failure to confine the use and possession of radioactive material to the specific sealed sources and model numbers authorized in the license. Accordingly, violation 030-32196/2017-001-05 is considered closed.

2.3.2 10 CFR 35.600 Photon Emitting Afterloader Units

The December 14, 2017, Inspection Report and NOV identified a Severity Level IV violation of 10 CFR 35.643(d), which requires in part, that spot-checks for remote afterloader units must, at a minimum, assure operation of the electrical interlocks at each remote afterloader unit room entrance (030-32196/2017-001-04).

The licensee responded to the NOV in a letter dated January 12, 2018. As corrective actions, the licensee verified the operability of the electrical interlocks, performed additional training to the AMPs on the required electrical interlock operability checks, and revised its checklist for high dose rate (HDR) remote afterloader brachytherapy.

During the portion of the inspection performed at St. Luke's Cancer Institute in Boise, Idaho, the inspector observed activities related to the licensee's Varian, Inc., Model VariSource iX HDR remote afterloader. The licensee also possessed an Elekta, Inc., Model Flexitron HDR remote afterloader at its St. Luke's Magic Valley Medical Center in Twin Falls, Idaho, which was not able to be observed during this inspection.

The inspector reviewed the licensee's implementation of its HDR remote afterloader brachytherapy program performed under 10 CFR 35.600. The inspector reviewed a selected sample of quality assurance checks, pre-treatment plans, written directives, and post-treatment radiation dose evaluations. Written directives were properly prepared and contained regulatory-required information. All HDR remote afterloader brachytherapy procedures reviewed could easily be followed from fraction to fraction, with fractions being performed appropriately and the total dose administered meeting the total prescribed dose. Pre-treatment and post-treatment quality assurance checks were performed for each dose fraction administered. All HDR remote afterloader brachytherapy procedures reviewed were of high quality and did not result in any medical events. The AMPs used an electronic checklist stored at the HDR console

computer to verify that the required elements of periodic spot-checks and other tests on the HDR remote afterloader unit were fulfilled.

The inspector observed an AMP perform the periodic spot-check of the licensee's VariSource iX HDR remote afterloader in preparation for a scheduled patient treatment. The inspector observed the HDR unit be set up for the spot-check and observed the performance of the spot-check. The AMP closely followed the detailed checklist for performing the spot-check. The checklist included verification of the operation of the electrical interlocks. The inspector observed the AMP test that: (1) the interlock prevented the treatment cycle from initiating unless the room entrance door is closed; (2) the radioactive source returned to the shielded position when the room entrance door was opened; and (3) the radioactive source would not be able to be exposed until the room entrance door was closed and the console was reset. The electric interlocks functioned as required in all instances.

The inspector observed a scheduled HDR remote afterloader brachytherapy patient procedure. Licensee personnel, including the AMP, Authorized User (AU), Radiation Safety Officer (RSO), and other staff were familiar with the licensee's operating and emergency procedures for the HDR remote afterloader. All required emergency equipment was available, and the emergency procedures were properly posted. In-room radiation monitors functioned as required. The AMP performed required radiation surveys with a calibrated hand-held radiation survey instrument. Licensee staff performed verification of the patient's identification and the prescribed dose on the written directive prior to the start of the procedure and utilized time-outs throughout the process.

The licensee's corrective actions were sufficient to address and to prevent recurrence of the previously identified violation regarding the failure to assure operation of electrical interlocks at the remote afterloader unit room entrance. Accordingly, violation 030-32196/2017-001-04 is considered closed.

2.4 Conclusions

The inspector reviewed the licensee's corrective actions related to two previously identified Severity Level IV violations regarding the licensee's failure to: (1) confine the use and possession of radioactive material to the specific sealed sources and model numbers authorized in the license; and (2) assure operation of electrical interlocks at the remote afterloader unit room entrance. Based on the NRC's inspection, both violations are considered closed.

3.0 Medical Event (IP 87103, 87131)

3.1 Inspection Scope

On February 24-28, 2020, the inspector performed an unannounced, routine inspection of SLRMC. This inspection included a review of a February 20, 2019, medical event involving the therapeutic use of Ra-223. To evaluate this matter, the inspector reviewed records, procedures, and documents maintained by the licensee, observed licensed activities, and interviewed personnel.

3.2 Background

Therapeutic administration of Ra-223 is authorized by NRC License 11-27312-01, under 10 CFR 35.300. Radium-223 dichloride, manufactured by Bayer under the product name Xofigo, is an alpha-emitting radioactive therapeutic agent indicated for the treatment of patients with certain types of prostate cancer and bone metastases. The dose regimen of Xofigo is 1.49 microcuries per kilogram (kg) body weight, given at four-week intervals up to a total of six injections. Each Xofigo patient dose is ordered by the licensee via a phone call to Cardinal Health Nuclear Pharmacy Services, who distributes Xofigo to authorized customers. The patient-specific radiopharmaceutical dose based on the patient weight is shipped directly to the licensee. The Ra-223 dose is administered to the patient by slow venous injection over one minute.

The licensee is authorized to perform activities under 10 CFR 35.300 at several of its facilities throughout Idaho, but in practice only performed activities involving Ra-223 at its main hospital in Boise, Idaho, and at St. Luke's Magic Valley Medical Center, in Twin Falls, Idaho.

3.3 Notifications/Reports to the NRC

On August 30, 2019, the NRC was notified by the licensee of a medical event, Event Notification (EN) 54250. In its notification and subsequent dialogue with an NRC inspector, the licensee related that during a routine audit, it identified an occurrence where a patient was administered a different dose of Ra-223 than what was prescribed on the written directive. The licensee stated that the patient was actually administered the appropriate and correct activity of Ra-223 but that an incorrect prescribed activity was indicated on the written directive. The medical event occurred on February 20, 2019, at the licensee's St. Luke's Magic Valley Medical Center, in Twin Falls, Idaho.

10 CFR 35.3045(a)(1)(i) requires, in part, that a licensee report any event in which the administration of byproduct material results in a dose that differs from the prescribed dose by more than 0.5 Sv (50 rem) to an organ or tissue, and the total dose delivered differs from the prescribed dosage by 20 percent or more.

For this administration, based on the patient's weight, the patient was supposed to be administered 83 microcuries of Ra-223, but the incorrectly prepared written directive stated that the patient was to be administered 56 microcuries of Ra-223. The patient was administered 83 microcuries of Ra-223 as intended. The error in the written directive was not identified at the time of administration.

The licensee discovered the medical event during an audit performed on August 29, 2019. The licensee determined that although the patient was issued the "correct" activity, it differed from the activity on the written directive. Based on a comparison with the incorrectly completed written directive, the dose delivered to the target organ/tissue (bone) was greater than 50 rem from what would have been received and the total dose delivered differed from the prescribed dosage by 20 percent or more. Therefore, this met the criteria for reporting of medical events in 10 CFR 35.3045(a)(1)(i).

10 CFR 35.3045(c) requires that the licensee notify the NRC Operations Center no later than the next calendar day after discovery of the medical event. The licensee discovered the medical event during an audit performed on August 29, 2019, and

reported it to the NRC Operations Center on August 30, 2019, no later than the next calendar day after discovery.

10 CFR 35.3045(d) requires, in part, that the licensee submit a written report to the appropriate regional office within 15 days of the discovery of the medical event. The licensee provided its written report to the NRC Region IV Office on September 3, 2019, within 15 days of the discovery of the medical event (ADAMS Accession No. ML19253C566).

The inspector determined that the medical event did not meet the NRC's criterion to be considered an Abnormal Occurrence. The licensee did not anticipate any adverse effects to the patient because the patient received the correct activity based on the patient's weight.

3.4 Causal Analysis

3.4.1 St. Luke's Regional Medical Center Causal Analysis

In its September 3, 2019, written report to the NRC, SLRMC noted that in this case, the written directive was filled out based on the assayed amount of radium-223 indicated by the reading on the dose calibrator. The licensee suspected that the patient dose was assayed or measured using an incorrect radionuclide setting on the dose calibrator, displaying an activity value that was much less than the actual activity contained in the vial. The licensee hypothesized that the written directive was then filled out with this incorrect information from the dose calibrator and provided to the AU for review and signature just prior to the patient administration.

In other words, the licensee believed that the correct activity of Ra-223 was ordered and delivered by Cardinal Health based on the patient's weight, and was 83 microcuries, but that licensee personnel measured or assayed the vial on the wrong dose calibrator setting, for a different radionuclide other than Ra-223. As a result, the dose calibrator displayed an incorrect activity of 56 microcuries, which was then documented on the written directive, which was signed and dated by the AU. The licensee's position was that although an error occurred, the patient received the intended activity (dosage) of Ra-223 but the documentation on the written directive was not reflective of the actual administration.

3.4.2 NRC Causal Analysis

10 CFR 35.41(a) requires, in part, that a written directive be properly prepared, dated, and signed by an AU prior to an administration of a therapeutic dose of radiation from byproduct material. The written directive must contain the patient's name, the radioactive drug, dosage, and route of administration. The inspector reviewed the written directive for the February 20, 2019, medical event. The written directive provided the patient name; radiopharmaceutical: Ra-223; dose: 56 microcuries; and route of administration: intravenous push. It was signed by the AU and dated February 20, 2019.

The lower portion of the written directive provided the "Radioactive Material Verification," in which the nuclear medicine technologist documented that the written directive was for 56 microcuries, the prescribed dose was 56 microcuries, and the dose calibrator reading was 56.6 microcuries on February 20, 2019, at 12:00 (Mountain Standard Time).

The inspector reviewed the Cardinal Health radiopharmaceutical vial label provided for the specific patient administration. The label had the patient's name and indicated that the dispensed activity was 85.61 microcuries with a calibration date and time of February 20, 2019, at 12:00 Eastern (Standard) Time, with an ordered activity of 83.10 microcuries. Accounting for radioactive decay, the vial should have assayed or measured as approximately 85.18 microcuries of Ra-223 at the time of administration. Although a medical event was required to be reported to the NRC by the licensee, it appears that based on the Cardinal Health radiopharmaceutical vial label, the patient did receive the intended activity of Ra-223 based on the patient's weight. The medical event, therefore, had no known consequences.

Although the licensee concluded that the Ra-223 vial must have been assayed or measured using an incorrect dose calibrator setting, they did not perform any analysis to verify this conclusion, although it would have been relatively easy to do so. A small reference dose of Ra-223 could have been ordered and utilized to measure on multiple dose calibrator radionuclide settings to determine if the same percent discrepancy could be reproduced.

The inspector concluded that it is unlikely that the patient dose was assayed or measured on an incorrect dose calibrator setting. The inspector concluded that the number 56 that was on the written directive was actually the patient's weight in kg as opposed to the desired Ra-223 activity. The inspector reviewed the patient's records and found in the patient's file, that the patient had been weighed for the prior Ra-223 administration, and that the patient's weight was indeed documented as 56 kg. Following the standard dosing protocol of 1.49 microcurie per kg body weight, the desired activity would have been 83.44 microcuries or Ra-223, which closely matches the ordered activity of 83.10 microcuries.

There is reasonable assurance that the patient received the desired and intended activity of Ra-223, but there were multiple deficiencies related to the preparation of the written directive and documentation of the radioactive material verification.

The inspector identified that a contributing cause that made the medical event more probable was the licensee not implementing best practices for therapeutic administrations of Ra-223 requiring a written directive. For example, although it is not required to indicate the patient weight on the written directive for Ra-223 dichloride (Xofigo), there is added value in documenting this information on the written directive so that there is a clear distinction between the patient weight (kg) and the prescribed activity or dosage (microcuries). Having the patient weight documented in kg allows for verification that the assayed or measured activity in microcuries does in fact match with the activity or dosage required based on the patient's weight.

Other best practices for therapeutic administrations of byproduct material requiring a written directive include, but are not limited to: having the prepared, signed, and dated written directive at the time of ordering the patient dose as opposed to just prior to the administration; and having a secondary verification of the dose calibrator assay or measurement.

The root cause is that which establishes the conditions that allow for the contributing causes to develop, which in turn, increases the probability of the occurrence of an event.

The inspector determined that the root cause of the medical event can be attributed to the ordering process for Ra-223 dichloride (Xofigo). When licensees order Xofigo from Cardinal Health, they are asked to provide the patient weight in kg (or pounds), as opposed to providing the requested activity of Ra-223 in microcuries. Cardinal Health then performs the simple calculation to determine the activity of Ra-223 needed. As such, licensee staff are accustomed to the patient weight being the relevant number for Ra223 dichloride (Xofigo) administrations. This practice has become so engrained that it reasonably resulted in the patient weight erroneously documented on the written directive instead of the required activity (dosage).

As noted above, the information provided in the February 20, 2019, written directive form included four instances where the incorrect activity was documented. Therefore, other errors would have had to occur for the incorrect activity on the written directive to not have been identified at the time of assay or measurement of the patient dose. Without fully understanding the errors, it is not possible to fully develop the causal factors or identify appropriate corrective actions. Unfortunately, the error occurred on February 20, 2019, and was not discovered by the licensee until August 29, 2019, and too much time had passed from incident to discovery to reasonably reconstruct the specific occurrence or reasonably rely upon staff or AU recollection of an otherwise unremarkable Ra-223 administration.

3.5 Inspection Findings

The inspector performed a review of a selected sample of other Ra-223 dichloride (Xofigo) administrations performed by the licensee. The selected sample was limited to the records of Xofigo administrations performed at the SLRMC main hospital in Boise, Idaho, and did not include records from St. Luke's Magic Valley Medical Center, in Twin Falls, Idaho. The inspector reviewed records for seven patients, each with from one to six Xofigo administrations, depending on the position of their administration cycle. Each administration had a separate written directive, since the patient's weight will vary and the required activity of Ra-223 is dependent on the patient's weight. In all, the inspector reviewed 23 separate Xofigo administrations requiring written directives.

For each Ra-223 dichloride (Xofigo) administration, the inspector's review included: the patient's documented weight prior to the procedure; the Cardinal Health vial sticker indicating activity ordered and calibrated activity; the completed written directive; and the completed "Radioactive Material Verification." The February 20, 2019, error in preparing the written directive appears to be an isolated occurrence. The inspector's review did not reveal any similar occurrence of an incorrect activity documented on a written directive and did not identify any additional medical events.

3.6 Corrective Actions

As a corrective action, the licensee staff were provided additional training regarding the licensee's policies regarding properly prepared, signed, and dated written directives. The licensee also noted that written directives will be audited quarterly by the RSO or designee. The licensee presented its conclusions and completed corrective actions at its December 6, 2019, Radiation Safety Committee meeting.

3.7 Conclusions

On August 30, 2019, the licensee notified the NRC of a medical event that met the criteria in 10 CFR 35.3045(a)(1)(i) (Event Number 54250). The medical event occurred on February 20, 2019, but was not discovered until the licensee performed an audit on August 29, 2019. On September 3, 2019, the licensee provided the NRC with a written report regarding the medical event. The licensee determined that the patient was administered the correct activity of Ra-223 dichloride (Xofigo) based on the patient's weight, but that an incorrect value of activity (dosage) was documented on the written directive.

The licensee implemented corrective actions following the discovery of the medical event, including proving additional training to relevant staff regarding its policy for the completion and preparation of written directives, and that written directives will be audited quarterly by the RSO or designee.

4.0 Dosimetry Program (IP 87131, 87132)

4.1 Inspection Scope

On February 24-28, 2020, the inspector performed an unannounced, routine inspection of SLRMC. This inspection included a review of the licensee's dosimetry program. To evaluate this matter, the inspector reviewed records, procedures, and documents maintained by the licensee, observed licensed activities, and interviewed personnel. Following the onsite inspection, the inspector reviewed additional information that was provided by SLRMC.

4.2 Background

10 CFR 20.1502 requires, in part, that each licensee shall monitor exposure to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits of 10 CFR Part 20. At a minimum, each licensee shall monitor exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and shall supply and require the use of individual monitoring devices by adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in 10 CFR 20.1201(a).

The inspector identified that Interventional Radiology (IR) physicians involved with yttrium-90 microsphere (Y-90) administrations at SLRMC had not worn or had improperly worn or stored their assigned individual monitoring devices, also called personnel dosimeters. Personnel dosimeters are used by the licensee to measure the radiation dose to occupationally exposed individuals. At SLRMC the IR physicians are contract employees from Boise Radiology Group and are listed as AUs on the SLRMC license.

The IR physicians were involved with both NRC licensed and unlicensed activities at SLRMC. Licensed activities that the IR physicians participated in primarily involved the use of Y-90, as authorized in NRC Materials License 11-27312-01, under 10 CFR 35.1000. The IR physicians were also involved with unlicensed activities at SLRMC. These activities, which included the use of radiation-producing devices, such as

fluoroscopes and other x-ray generating devices, are called “unlicensed” or “non-licensed” because they are not licensed by the NRC.

It was determined that since the inception of the SLRMC Y-90 microspheres program, there were six IR physicians who were involved with both licensed and non-licensed activities at SLRMC. At the time of the inspection, two of these IR physicians had not been involved with the Y-90 microspheres program for several years and were not considered to be active AUs for 10 CFR 35.1000. For the purposes of Section 4 of this report, the remaining four IR physicians who were active AUs are referred to by number, as IR1 through IR4.

Both IR3 and IR4 did not wear their assigned personnel dosimeters for several months a year, for several years, and during the months that the dosimeters were worn, they do not appear to have been worn routinely or properly throughout the month. Both IR1 and IR2 had higher levels of compliance with wearing personnel dosimeters, but were not fully compliant, in that there were a few months that the dosimeters were not worn. For IR1, there were also instances where the assigned dosimeter was improperly stored and potentially subjected to radiation when the dosimeter was left on their lead apron hanging in the IR procedure room.

4.3 Radiation Dose Evaluation

During the onsite inspection, the scope and extent of the IR physician dosimeter issue could not be fully understood by the inspector. Historical dosimetry records and information from prior RSOs were not readily available during the inspection. At the conclusion of the onsite inspection, the inspector requested that a radiation dose evaluation be performed for the four IR physicians who were engaged in licensed and non-licensed activities.

The licensee provided its radiation dose evaluation to the NRC on March 10, 2020 (ADAMS Accession No. ML20112F341). The NRC reviewed the licensee’s evaluation and provided several follow-up questions to the licensee for additional clarification. On April 15, 2020, the licensee responded to the follow-up questions and provided a revised radiation dose evaluation for the four affected IR physicians, going back to CY 2012 (ADAMS Accession No. ML20112F337).

Dosimeter use by the IR physicians varied considerably per CY. Two IR physicians were fairly complaint with dosimeter use but still had months where dosimeters were not worn. Two other IR physicians had several months each year with no dosimeter use. A simplistic indicator of no dosimeter use is an unused monthly dosimeter or a monthly dosimeter with a reading of “M” for months where the number of IR cases was greater than zero (0). A dosimeter reading of “M” stands for “minimal,” meaning that after the control dosimeter reading is subtracted from the personnel dosimeter reading, the resulting radiation dose was below the minimal reporting capabilities of the dosimeter.

Table 1 provides a summary of the number of unused or “M” dosimeters for the four IR physicians. This simplification is illustrative of the scope and extent of the issue but does not take into account months where dosimeters had a reading greater than zero but that reading was inconsistent with the number of IR cases performed that month.

In determining its approach to assessing the radiation dose to the four IR physicians, the licensee decided to not consider the dosimeter results for any of the IR physicians for any of the years evaluated. There was insufficient dosimetry data for IR3 and IR 4, and there were concerns about inappropriate dosimeter storage for IR1.

	2012	2013	2014	2015	2016	2017	2018	2019
IR1						0	2	0
IR2			0	2	2	1	0	0
IR3		2	5	6	11	2	7	6
IR4	10	10	8	8	10	8	8	11

Table 1: Number of monthly personnel dosimeters returned unused or had minimal readings “M”

In order to make radiation dose assessment for the four IR physicians, the licensee gathered readily retrievable fluoroscopy time information related to IR procedures for CY 2019. For CY 2018 and CY 2017, fluoroscopy time information was not available, but the number of IR procedures performed by the four individuals was available.

The licensee conducted interviews with the IR physicians to gather information regarding the standard setup for various IR procedures, the use of various fluoroscopy modes, and the typical position of the IR physician relative to the radiation beam during IR procedures. Based on the information gathered, the licensee utilized a representative fluoroscopy unit in a standard IR procedure room to obtain representative radiation measurements. The licensee replicated a patient procedure using 30 centimeters of water in a plastic bucket as a simplified patient phantom. The radiation beam was collimated to a field size that was representative of the average field size used for IR procedures. The licensee then collected multiple radiation measurements at representative distances using both “Normal/Standard” and “Cine” fluoroscopy modes. Cine mode produces a higher radiation exposure rate than Normal mode. Radiation measurements were taken by the licensee with a calibrated ion chamber survey meter from behind a shield that provided 0.5 millimeters of lead attenuation.

With the collected data, the licensee used several conservative assumptions in making its radiation dose assessment for the four IR physicians. The licensee assumed that: (1) the IR physician was in the IR procedure room during every Cine run, although IR physicians normally leave the IR procedure room during Cine runs; (2) every IR procedure had a Cine mode component which accounted for 10 percent of the total procedure exposure, although not all IR procedures have a Cine mode component; and (3) the remaining 90 percent of the procedure exposure was attributed to Normal mode. These assumptions are conservative but not overly conservative and would therefore result in a reasonable value that would not be expected to underestimate the radiation dose.

The license searched its records and identified the month and year that each IR physician first participated in Y-90 activities at SLRMC. The number of Y-90 procedures per IR physician was easily retrievable for CY 2019. One IR physician did not work with Y-90 or engage in licensed activities at SLRMC prior to CY 2018. For the other three IR physicians, for CY 2012 through CY 2018, the licensee assumed that each individual performed some amount of Y-90 procedures (a licensed activity) during each CY, although the number of Y-90 procedures could not be readily determined.

The number of IR procedures for CYs 2012 through CY 2016 for the IR physicians was not retrievable but was conservatively assumed by the licensee to be the highest number of IR cases from CY 2017 through CY 2019. For three individuals, this was CY 2018, which represented a high-volume year just prior to changes made by SLRMC in the assignment of IR procedures, which reduced the IR procedures per IR physician volume in CY 2019.

A summary of the licensee's radiation dose evaluation is provided in Table 2. The licensee's evaluation concluded that there were no exposures in excess of NRC's regulatory limit of 5 rem total effective dose equivalent for any IR physician for any year evaluated.

	2012	2013	2014	2015	2016	2017	2018	2019
	IR1							
Recorded Dosimeter Dose (mrem)						1709	1403	1543
Licensee Estimated Dose (mrem)							1186	1005
Estimated IR cases						760	744	631
Y-90 cases						0	>1	21
	IR2							
Recorded Dosimeter Dose (mrem)			1415	634	589	1078	529	896
Licensee Estimated Dose (mrem)			2115	2115	2115	2015	2115	1652
Estimated IR cases			735	735	735	704	735	576
Y-90 cases			>1	>1	>1	>1	>1	3
	IR3							
Recorded Dosimeter Dose (mrem)		191	147	16	2	928	339	60
Licensee Estimated Dose (mrem)		386	1142	1142	1142	1029	1142	944
Estimated IR cases		820	820	820	820	741	820	680
Y-90 cases		>1	>1	>1	>1	>1	>1	7
	IR4							
Recorded Dosimeter Dose (mrem)	121	8	42	12	6	10	10	2
Licensee Estimated Dose (mrem)	1498	1498	1498	1498	1498	1406	1498	1019
Estimated IR cases	762	762	762	762	762	715	762	520
Y-90 cases	>1	>1	>1	>1	>1	>1	>1	13

Table 2: Summary of Licensee Radiation Dose Data for IR Physicians

The inspector evaluated the licensee's radiation dose estimates and determined that the licensee's approach and assumptions were sound and comprehensive. Additionally, the inspector found that the licensee's methodology would not be expected to underestimate the radiation dose and resulted in conservative but reasonable radiation dose estimates for the four IR physicians.

4.4 Causal Evaluation

The licensee did not perform a formal causal evaluation but identified that the education and training materials previously provided to the IR physicians were not adequate to ensure that wearing or usage of personnel dosimeters was a priority.

The inspector identified that the IR physician training was a contributing cause that made it more probable that the IR physician personnel dosimetry failure would occur. However, the inspector identified that the root cause, whose existence establishes the

conditions that allow for any contributing causes to develop, was the licensee's failure to develop and implement a radiation protection program, including policies, procedures, and training programs, commensurate with the scope and extent of licensed activities.

The inspector identified that the IR physicians, as contractors to SLRMC, were inadvertently not included in the licensee's training program regarding personnel monitoring. As a result, the IR physicians had not received training on: (1) the NRC's regulatory requirements regarding the monitoring of both licensed and unlicensed activities; and (2) SLRMC's policies and procedures regarding proper dosimeter use and storage.

The IR physician personnel dosimeter use issue was identified by the inspector during the inspection. The existing SLRMC quarterly auditing practices for evaluating personnel dosimeter results were effective in identifying high or unusual dosimeter readings but were not effective in identifying a lack of dosimeter use (i.e. unused dosimeters or "M" readings) or unexpectedly low dosimeter readings (i.e. 2 millirem total effective dose equivalent for 820 IR cases). As a result, the licensee was unaware of the non-compliance.

4.5 Inspection Findings

Three apparent violations were identified regarding the licensee's failure to: (1) monitor individuals' occupational exposure to radiation and radioactive material; (2) implement a radiation protection program commensurate with the scope and extent of licensed activities; and (3) provide instruction to occupationally exposed individuals.

Apparent violation of 10 CFR 20.1502

10 CFR 20.1502 requires, in part, that each licensee shall monitor exposure to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits of 10 CFR Part 20. At a minimum, each licensee shall monitor exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and shall supply and require the use of individual monitoring devices by adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in 10 CFR 20.1201(a).

Contrary to the above, from January 1, 2012, to February 24, 2020, the licensee failed to monitor individuals' occupational exposure to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits of 10 CFR Part 20. Specifically, for four IR physicians, the licensee failed to monitor their occupational exposure to radiation from licensed and unlicensed radiation sources under the licensee's control and failed to require the use of individual monitoring devices by the IR physicians, who were likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in 10 CFR 20.1201(a), and had a substantial potential to exceed the NRC's annual limit in 10 CFR 20.1201(a).

The licensee's failure to monitor individuals' occupational exposure to radiation and radioactive material was identified as an apparent violation of 10 CFR 20.1502. (030-32196/2020-001-01)

Apparent violation of 10 CFR 20.1101(a)

10 CFR 20.1101(a) requires, in part, that each licensee implement a radiation protection program commensurate with the scope and extent of licensed activities sufficient to ensure compliance with 10 CFR Part 20.

Licensee policy EC046 BMW, "Occupational Radiation Exposure Program (ALARA - As Low As Reasonably Achievable)," Revision effective August 2, 2009, Section III.B and licensee policy EC046 SLHS, "Radiation Exposure Monitoring Program (ALARA)," Revisions effective December 12, 2012, through October 15, 2019, Section III.H, state, in part, that for personnel dose less than the Investigational Level: except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's dose is less than the Table 1 values for ALARA Level I.

Contrary to the above, from January 1, 2012, to February 24, 2020, the licensee failed to implement a radiation protection program commensurate with the scope and extent of licensed activities sufficient to ensure compliance with 10 CFR Part 20. Specifically, the licensee's policies EC046 BMW and EC046 SLHS failed to include provisions regarding actions to be taken when dosimeters were less than the licensee's ALARA I Investigational Level, such as those dosimeters that were returned unused or had unexpectedly low exposures.

The licensee's failure to implement a radiation protection program commensurate with the scope and extent of licensed activities was identified as an apparent violation of 10 CFR 20.1101(a). (030-32196/2020-001-02)

Apparent violation of 10 CFR 19.12(a)(3)

10 CFR 19.12(a)(3) requires, in part, that all individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 100 mrem shall be instructed in, and required to observe, to the extent within the worker's control, the applicable provisions of the Commission regulations and licenses for the protection of personnel from exposure to radiation and/or radioactive material.

Contrary to the above, from January 1, 2012, to February 24, 2020, the licensee failed to provide instruction to individuals who in the course of employment were likely to receive in a year an occupational dose in excess of 100 mrem, on the applicable provisions of the Commission regulations and licenses for the protection of personnel from exposure to radiation and/or radioactive material. Specifically, the licensee failed to provide adequate instructions regarding the proper use and storage of personnel dosimeters to four IR physicians who were likely to receive in a year an occupational dose in excess of 100 mrem.

The licensee's failure to provide instruction to occupationally exposed individuals was identified as an apparent violation of 10 CFR 19.12(a)(3). (030-32196/2020-001-03)

4.6 Corrective Actions

Following the inspection, the licensee implemented several corrective actions to address the personnel dosimetry issue. The licensee: (1) provided training to the contracted IR physician group regarding the licensee's policies and NRC regulations regarding personnel monitoring; (2) committed to ensuring that the contracted IR physician provider group is enrolled in the licensee's annual Radiation Safety and Education training module, which describes the requirements for radiation monitoring and employee responsibilities; (3) committed that over the following 12 months the RSO would report the dosimetry results of all Y-90 IR physicians to the SLRMC Radiation Safety Committee and assess whether these exposures are appropriate for the workload during the wear period; and (4) obtained signed "Provider TLD Badge Compliance Attestation" forms from the IR physician group members.

4.7 Conclusions

The inspector identified that four IR physicians involved with Y-90 administrations had not consistently worn or had improperly stored their assigned personnel dosimeters, which are intended to be used to monitor radiation dose to the individuals. At the NRC's request, the licensee performed a retrospective evaluation of the radiation dose received by the IR physicians from CY 2012 through CY 2019. The licensee's evaluation concluded that there were no exposures in excess of NRC's regulatory limit for any IR physician for any year evaluated.

Three apparent violations were identified regarding the licensee's failure to: (1) monitor individuals' occupational exposure to radiation and radioactive material; (2) implement a radiation protection program commensurate with the scope and extent of licensed activities; and (3) provide instruction to occupationally exposed individuals.

The root cause of the failures associated with the SLRMC dosimetry program can be attributed to the licensee's failure to develop and implement a radiation protection program, including policies, procedures, and training programs, commensurate with the scope and extent of licensed activities.

Following the onsite inspection, the licensee implemented several corrective actions to address the personnel dosimetry deficiencies. These corrective actions included providing additional oversight of the SLRMC personnel dosimetry program and providing individuals with instruction regarding the licensee's policies and the NRC's regulations regarding personnel monitoring.

5 Exit Meeting Summary

On June 25, 2020, a final telephonic exit meeting was conducted with the Vice President, Quality Operations and Patient Safety, and other members of the SLRMC staff to discuss the inspection findings. The NRC representatives described the NRC's enforcement process and the options for the licensee to: (1) respond in writing to the apparent violations addressed in the inspection report; (2) request a predecisional enforcement conference, or (3) request alternative dispute resolution.

Supplemental Inspection Information

PARTIAL LIST OF PERSONS CONTACTED

Jodi Vanderpool, Vice President, Quality Operations and Patient Safety
Scott Fuller, MS, DABR, RSO and Director of Radiation Safety
James Blacker, MS, Assistant Director of Radiation Safety
Christopher Jennings, MD, Authorized User and Radiation Safety Committee Chair
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Jennifer LaRue, CNMT, RT(N), Nuclear Medicine Technologist
Laura Plunkett, Patient Care
Kim Frost, Patient Care

INSPECTION PROCEDURES USED

87103	Inspection of Material Licensees Involved in an Incident or Bankruptcy Filing
87131	Nuclear Medicine Programs, Written Directive Required
87132	Brachytherapy Programs

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

030-32196/2020-001-01	AV	Failure to monitor individuals' occupational exposure to radiation and radioactive material. (10 CFR 20.1502)
030-32196/2020-001-02	AV	Failure to implement a radiation protection program commensurate with the scope and extent of licensed activities. (10 CFR 20.1101(a))
030-32196/2020-001-03	AV	Failure to provide instruction to occupationally exposed Individuals. (10 CFR 19.12(a)(3))

Closed

030-32196/2017-001-04	VIO	Failure to assure operation of electrical interlocks at the remote afterloader unit room entrance. (10 CFR 35.643(d))
030-32196/2017-001-05	VIO	Failure to confine the use and possession of radioactive material to the specific sealed sources and model numbers authorized in the license. (License Condition 7.D.)

Discussed

None

LIST OF ACRONYMS AND ABBREVIATIONS USED

ADAMS	Agencywide Documents Access and Management System
ADR	Alternative Dispute Resolution
ALARA	As Low As is Reasonably Achievable
AMP	Authorized Medical Physicist
AV	Apparent Violation
AU	Authorized User
CFR	*Code of Federal Regulations*
CY	calendar year
EN	Event Notification
HDR	High Dose Rate
IP	Inspection Procedure
IR	Interventional Radiology
kg	kilogram
NRC	Nuclear Regulatory Commission
NOV	Notice of Violation
PEC	Pre-decisional Enforcement Conference
Ra-223	radium-223 dichloride (Xofigo)
RSO	Radiation Safety Officer
SLRMC	St. Luke's Regional Medical Center
VIO	Violation
Y-90	yttrium-90